UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Suzanne Genereux, et al.)
Plaintiffs,))) Case No. 04-CV-12137 JLT
V.)
American Beryllia Corp., et al.))
Defendants.)

PLAINTIFFS' EXPERT AFFIDAVIT BY JOHN W. MARTYNY, Ph.D.

- 1. I was asked by counsel for the plaintiff to prepare a report regarding beryllium exposures to Mrs. Suzanne Genereux who worked at the Raytheon facility located in Waltham, Massachusetts. Mrs. Genereux worked at the Waltham facility from 1982 through 1990.
- 2. This report provides my expert opinion regarding such exposures while working at that facility, and the related issues of risk, the necessity and adequacy of warnings, and industrial hygiene considerations. All of the opinions contained in this report are expressed within a reasonable degree of scientific certainty and are based on my personal knowledge, training, education, and experience.
- 3. I am an Associate Professor employed by the Division of Environmental and Occupational Health Sciences at the National Jewish Medical and Research Center in Denver, Colorado. I am also an Assistant Professor in the Preventive Medicine and Biometrics Department at the University of Colorado

School of Medicine. I am a Certified Industrial Hygienist certified by the American Board of Industrial Hygiene since 1987.

- 4. My experience with beryllium and beryllium exposures dates from the mid 1980's when I participated in an epidemiological investigation of chronic beryllium disease at the former Rocky Flats Nuclear Weapons Plant. At that time I conducted an industrial hygiene evaluation of exposure data obtained at the plant, as well as interviewing numerous beryllium workers at the facility. The results of the study were published in 1993 in the American Review of Respiratory Diseases.⁽¹⁾
- 5. Since that time, I have been involved with different beryllium facilities throughout the United States and Canada. I have conducted many industrial hygiene investigations at government and private facilities as well as advising beryllium facilities regarding employee protection. I have been a participant in several beryllium epidemiological studies and have conducted beryllium research projects of my own. (2 7) It is because of this experience that I was asked to write this report. My qualifications and publications are detailed in my Curriculum Vitae, which is attached to this report.

Background:

6. Beryllium is a silver-gray metal known for its lightness, stiffness, corrosion-resistance, and ability to disperse heat rapidly. In addition, when alloyed with other metals (e.g. copper or aluminum) it tends to pass on these qualities to the primary metals. For these reasons, it is widely used both as an

alloy and as a pure metal in a variety of high technology and aerospace applications. Beryllium also has a strategic importance in that it is a source of both low and high-energy neutrons when bombarded by other nuclear radiation and is therefore utilized in the manufacture of nuclear weapons. (8)

- Pulmonary illness associated with beryllium was identified in the 7. 1930's by German, Italian, and Russian scientists and in the early 1940's by U.S. scientists. (9) These initial reports were primarily concerned with the acute phase of the disease. The initial instances of chronic beryllium disease were recognized in the fluorescent lamp industry in 1946, where beryllium was utilized in the phosphors of the lamps. (10) In 1947, a symposium was held in Saranac lake, New York to discuss the emerging concern regarding pulmonary disease and beryllium.
- The scientific information presented at this meeting initiated a number 8. of investigations into the health effects of beryllium and, in fact, signaled the beryllium community that pulmonary disease was associated with beryllium exposure. (11)
- 9. Because of this evidence of pulmonary disease associated with exposure to beryllium, the U.S. Atomic Energy Commission began a study of beryllium exposures and beryllium disease at the Brush Beryllium Company facility (now Brush Wellman, Inc.) located in Lorain, Ohio. This investigation was conducted by Dr. Merril Eisenbud who, at the time, was employed by the Atomic Energy Commission and in later years was a consultant for Brush Wellman, Inc.

(Brush Wellman). This report was the first study to suggest that very low levels of beryllium exposure could cause chronic beryllium disease (CBD).

- 10. The study indicated that CBD was found in non-occupational exposures at distances up to ¾ of a mile from the plant and that exposures at that location were in the range of 0.03 ug/m³. The average concentrations near the plant site ranged from 0.1 ug/m³ to 0.03 ug/m³. In the exhibit, the author suggests a level of 0.0025 as the population exposure level although subsequent documents from Dr. Eisenbud suggest 0.01 ug/m³ as the neighborhood exposure limit. (12)
- 11. In late 1948, Dr. Eisenbud, in conjunction with Willard Machle, (12) developed an exposure standard for beryllium based upon the exposure values for heavy metals and adjusted for the low atomic weight of beryllium (molecular weight of 9). The recommended exposure value was determined by taking the average heavy metal exposure limit (100 ug/m³) and dividing it by 20 (Be has an atomic weight approximately 1/20th of heavy metals).
- 12. The resulting 5 ug/m³ was reduced to 2 ug/m³ for a safety factor and was recommended as a maximum beryllium exposure level for use by Atomic Energy Commission contractors. They also suggested the neighborhood standard of 0.01 ug/m³. These levels have been continued to the present day, with some minor changes. The United States Environmental Protection Agency adopted the neighborhood level in 1973 as an ambient air quality standard. (8)
- 13. In 1954, Dr. Eisenbud presented a paper to the American Society for Metals documenting the state of knowledge regarding beryllium exposures. The

AEC advisory committee set the following guidelines for contractors working with beryllium:

- a. The in-plant concentration of beryllium should not exceed 2 ug/m³ as an average concentration for an 8-hour day.
- b. Even if the exposures are within that level, no personal should be exposed to over 25 ug/m³ for any period of time.
- 14. The current Occupational Safety and Health (OSHA) permissible exposure level (PEL) is 2 ug/m³ measured as an 8-hour time-weighted average. This level was adopted in 1971 in 29 CFR1910.1000 of the Code of Federal Regulations. The PEL is different than the AEC level in that the regulation requires the following: "An employee's exposure to any substance listed in Table Z-2, in any 8-hour work shift of a 40-hour work week, shall not exceed the 8-hour time weighted average limit for that substance in Table Z-2. (10)
- 15. Based on the OSHA Standard, any 8-hour exposure above the PEL is a violation. There is **no** 60 day averaging allowed in the regulation for any substance listed in Table Z-2. The standard does allow single exposures of less than 30 minutes to as much as 25 ug/m³ and a ceiling value of 5 ug/m³.
- 16. Under these regulations, a 35 minute exposure of over 5 ug/m³ for a single shift is a violation. Since these levels apply to all employees, it stands to reason that the level of exposure for all employees must be determined, either directly or by association.

- 17. The same occupational level of 2 ug/m³ was adopted by the American Conference of Governmental Industrial Hygienists as the threshold limit value (TLV). These levels are some of the lowest allowable exposure levels promulgated and testify to the ability of very small amounts of beryllium to cause illness in workers.
- 18. Two micrograms of beryllium in a cubic meter of air would not be visible as a dust to the naked eye and therefore, the absence of a visible dust does not offer protection to employees. In fact, only industrial hygiene sampling for a period of time can document the actual exposure.
- 19. In 1972, NIOSH published a criteria document concerning beryllium. (11) The document specified an 8 hour time-weighted average of 2 ug/m³ as the recommended exposure limit (REL) and a 25 ug/m³ ceiling. NIOSH did state in the document that although adherence to the standard would bring exposure levels to below typical exposures observed in the 1940's, the actual safety factor of the standard was unknown. The authors stated that there still had been no comprehensive, long-term controlled study that related beryllium concentration to chronic beryllium disease. In 1977, NIOSH published a second Criteria Document that proposed a lower standard of 0.5 ug/m³. (14)
- 20. This revised standard was not initiated because of chronic beryllium disease rates but rather it was issued due to concerns with the carcinogenicity of beryllium. The document indicated that the current standard may or may not be protective but found in several studies of the industry that none of the three

existing beryllium facilities were meeting the current standard. The authors indicated that controls could be used to reduce exposures but that they had not been implemented.

- 21. Immediately after the setting of the AEC beryllium exposure standard, it seemed that the lowered exposure levels were controlling, not only acute beryllium disease, but also chronic beryllium disease.
- 22. In the early 1980's however, chronic beryllium disease returned to the scene. In 1983 three cases of CBD were reported in a spacecraft manufacturing plant. In 1979, Rom et al. found a 15.9% rate of beryllium sensitization among 82 employees at a surface mine and process mill near Delta, UT. A follow-up study in 1982 identified a sensitization rate of 8.9% in a group of 61 workers. In 1987, Cullen et al for discovered CBD in a precious metal refinery where air concentrations of beryllium were felt to be below the current 2 ug/m³ standard.
- 23. In 1989 a study by Kreiss et al at a nuclear weapons plant identified a 11.8% beryllium sensitization rate in 51 machinists with five of the six sensitized individuals having CBD. (18) A second study conducted by Kreiss et al at the same facility, identified a 2% rate of sensitization in nuclear weapons workers with most having actual CBD. (1) In 1993, a third study by Kreiss et al conducted in a ceramics plant identified sensitization rates ranging from 11.1% to 15.8% among some workers with most exposures appearing to be below the current standard using the DWA method of sampling. (19) A study by Yoshida and Shima, et al.

reported beryllium sensitized workers in a beryllium copper plant even though exposures were below the current 2 ug/m³ standard. (20)

- 24. Based on these studies, two general conclusions can be made:
 - a. CBD has not been eliminated in the workplace and the current standard of 2 ug/m³ is probably not protective for a large number of exposed workers. In response to these revelations, the U.S.
 Department of Energy (DOE) established a Chronic Beryllium Disease Prevention Program in 1999. Among a number of changes, this program set a level of 0.2 ug/m³ as the action level for DOE facilities. Although this change did not officially change the standard, it signaled that the levels of concern for beryllium are well below the current PEL, a fact that was well known throughout the beryllium industry, including Brush Wellman and National Beryllia Corporation, predecessor in interest to the defendant American Beryllia ("ABC"), starting in at least the early 1980's.
 - b. In addition, the ACGIH is also proposing a lower standard for beryllium⁽²¹⁾ and an authoritative article written by an industrial hygienist for DOE has suggested that the actual exposure limit for beryllium should be 0.1 ug/m³.⁽²²⁾ Even Brush Wellman, who's industrial hygienists have steadfastly held to the 2.0 ug/m³ standard, are now using an action level of 0.2 ug/m³.

Industrial Hygiene Aspects of Beryllium:

- 25. Industrial hygiene principals applied to potentially hazardous exposures have been in existence since before the early 1970's and have included the recognition, evaluation, and control of these exposures. The first phase, recognition, involves the identification that a compound may cause a health problem if workers are exposed to sufficient levels of the material. The second phase involves the evaluation of the exposure.
- 26. Evaluation includes sampling to determine exact levels to which employees are being exposed. This is an extremely important step since simply deciding that a practice is safe without monitoring may result in employee over-exposure, especially when, in the case of beryllium, very low levels of the material cause disease. Methodologies to sample for beryllium have been readily available since the early 1950's and can be conducted by any competent industrial hygienist.
- 27. Initial beryllium sampling was conducted using the AEC methodology detailed at the time of the development of the standard in 1949. This methodology utilized high volume samplers to pull air through a 4 inch Whatman #41 filter for analysis. Samples were taken in the breathing zone of the worker or from general areas around the facility. The samples were normally taken for periods of 30 minutes or so and then sent to the laboratory for analysis. The results of the sampling were then applied to the individuals working at that job task. Based on the results, a daily-weighted average was calculated by

multiplying the average exposure for each job component by the amount of time spent by the operator for each component. The sum of the products for all of the components for each employee was then divided by the average work time for that employee per day to yield the time-weighted average for the job.

- 28. Although early analytic techniques may have required larger amounts of beryllium on a filter to accurately determine exposures, the AEC DWA method of sampling has several flaws that limit its usefulness in predicting actual exposures. The most glaring limitation is that this method does not actually hinge on what the employee is doing but rather looks at the process. Since most employees have different ways to get the same job done, there can be wide variations in exposure between different employees. In addition, the time monitored may not actually be representative of the actual exposures for that task. Employees may also have major exposures that are not observed by the industrial hygienist and therefore not sampled.
- 29. Recognizing these, as well as other limitations AEC methodology, Harry M. Donaldson (previously a Brush Wellman employee) and William Stringer compared three methodologies for beryllium sampling: personal sampling using lapel samplers, the AEC methodology, and personal respirable sampling. (23) The researchers found that none of the three methods were comparable and that the conversion of results from one type of sampling method to another was not possible.

- 30. They also found that personal samples worn by the workers gave results that were generally higher than were the results obtained using the AEC methodology. In several areas, the geometric means for the personal samples were over 1.5 times higher than the results obtained using the AEC methodology. The researchers attributed this difference to the difficulty in obtaining good time and motion information for employees, non-typical work tasks, and individual differences. The authors state that based on their research, accurate determination of the exposures of maintenance crews, decontamination workers, and others conducting non-routine jobs cannot be determined using the AEC methodology.
- 31. The new DOE Chronic Beryllium Disease Prevention Program (CBDPP)⁽¹⁴⁾ requires personal breathing zone samples of all persons who work in areas where there may be airborne concentrations of beryllium. It requires the employer to employ a statistically based program to make the determination of the sample numbers necessary to accurately predict exposures.
- 32. Although the CBDPP program is relatively new, the use of personal monitoring and the principals of exposure determination have been known to the profession for some time. The American Industrial Hygiene Association published "A Strategy for Occupational Exposure Assessment" in 1991 that provides several methodologies to design a sampling plan capable of determining employee exposures.

- 33. This publication also reiterates the belief that area sampling is not a substitute for personal monitoring and that personal monitoring must be done to accurately determine exposures. The book indicates that a mix of full shift sampling and process sampling must be employed to accurately determine processes exposures.
- 34. The last phase of an employee protection plan is to protect employees from exposures that do or could approach either the PEL or TLV, whichever is lower. In order to implement this phase, it is very important to determine the potential exposures so that the designed controls will reduce the exposures to below the current standards. It is also important that the controls to be employed can be easily utilized correctly by employees. A primary control utilized by many companies is respiratory protection. Respirators are commonly used because they are believed to be an inexpensive, quick method to use that requires very little capital cost. It is therefore, one of the most misused forms of protection for employees. In order to properly utilize respirators, employers must have a written respiratory protection plan that specifies: what respirators are to be used; how they are to be used; their limitations; maintenance and care.
- 35. In general, control methodologies should attempt to prevent a contaminant from entering the workers breathing zone. There are three processes frequently observed in general industry that I and others have found to actually increase worker exposures: dry sweeping, compressed air cleaning, and local fans. Although utilized to clean an area, the use of these processes causes settled

particulate to be re-suspended into the breathing air of the workers, which significantly increases exposures.

- 36. In all plants in which beryllium is used with which we have worked, we have immediately requested that employees stop using brooms, compressed air, and fans. Disturbing the dust within a beryllium facility results in an increase in the beryllium concentration in the general air of the plant and therefore an increase in worker exposure.
- 37. In the case of beryllium, the contaminant of concern is primarily beryllium aerosol that is of a respirable size (< 10 um in aerodynamic diameter). In fact, recent research conducted independently by ourselves and researchers at Brush Wellman (the U.S. producer of beryllium) have suggested that the most danger is from small particles with an aerodynamic diameter of less than 1.0 um. (4) In general, these aerosols are invisible unless a very large quantity of material is being produced. For this reason, any process that may generate a beryllium aerosol must be evaluated.
- 38. A major aerosol producer that resulted in very high exposures at Rocky Flats was simply polishing beryllium with a Scotchbright pad. Grinding, polishing, machining, welding, pickling, acid etching, and sparking beryllium are only some of the ways in which a beryllium aerosol can be produced and disseminated throughout a facility. In general, any process that disturbs the surface of beryllium material should be evaluated.

Beryllium Particulate Distribution in Beryllium Facilities:

- 39. Beryllium particulate generated from disturbance of the surface layer of the beryllium ceramic or metal will produce a number of different sized particles depending upon the type of disturbance utilized. Operations such as polishing and lapping will produce very small particles that tend to be present in the air for extended periods of time. Operations such as lathe operations may produce larger particles and even strips of metal that are so large that they can't be suspended in air. For most operations, however, a combination of small and large particles are generated. Research that I conducted indicated that most beryllium operations generate a significant amount of respirable particles that will be easily suspended in the air.
- 40. When particles that are less than 10 um in aerodynamic diameter are released into the air, they will remain suspended within the air for a significant amount of time. The smallest of these particles will, in fact, never leave the air unless they are removed using some air cleaning device. Once they are in the general air of the facility, the particles will be distributed throughout the area handled by that air handling device, which may include the entire building. For this reason beryllium contamination can usually be found at detectable levels throughout facilities that have allowed beryllium particulate to escape. Once the beryllium is in the general dust of the facility, the numbers of individuals that become exposed increase dramatically.

- 41. In addition to airborne release, uncontrolled processes also allow the spread of beryllium particulate throughout a facility on the clothes and shoes of the workers. Work conducted by myself and NIOSH at a beryllium machining facility found that high levels of beryllium may be spread around the plant on the clothing and shoes of workers. The spread will not only be in the specific building housing the beryllium process but also in adjacent buildings and even into the personal automobiles and trucks owned by the workers. As worker transportation becomes contaminated, so does the worker home environment. Because of this "take home" contamination, it is very common for the families of beryllium workers to become sensitized to beryllium and some even become CBD patients. Worker transportation of beryllium on their shoes and clothing has also been linked to a number of cases of chronic beryllium disease at a Nevada DOE facility where carpet contamination was linked to exposures to clerical staff within the building.
- 42. Steps to control the spread of beryllium contamination within a facility include: control of beryllium dust at the source, control of beryllium contaminated air, control of beryllium contaminated clothing, and control of beryllium on the workers. The first and most important step is to assure that beryllium particulate is not released into the air from any beryllium operation. This is accomplished by first, labeling all beryllium parts so that accidental work on the part does not happen in an uncontrolled area. In situations where beryllium has been sanded, filed, ground, or machined in the open, contamination to areas throughout the

building have been documented. A few uncontrolled operations have resulted in significant beryllium contamination within many buildings in the DOE complex.

- 43. The second most important control point is to collect all of the beryllium dust released by a process using a local exhaust control system.

 Although a glove-box may be the most effective control measure, there are a number of local exhaust devices that can be designed to capture all or most all beryllium particulate generated by that process. An uncontrolled process will essentially allow all of the beryllium particulate generated into the environment which, in turn will allow spread of the particulate by air currents and inadvertent employee transport.
- 44. As mentioned above, a major source of contamination for beryllium workplaces and worker residences is residual beryllium on the clothing and bodies of beryllium workers. A number of studies have shown that re-suspension of beryllium dust from the clothing of workers has resulted in significant exposure to the worker as well as other workers and the families of workers. Cases of chronic beryllium disease in spouses have been linked to the handling of contaminated clothing at home. Brush Wellman, Inc., as well as most other beryllium manufacturing facilities, have long required workers to wear work clothes while working with beryllium. These work clothes are required to be changed prior to going home or, in some cases, prior to leaving the beryllium-contaminated area. The clothes change area is usually located outside of the beryllium area and has a dirty and clean side designed to reduce beryllium spread throughout the facility.

Shoes are also required to be changed prior to leaving the beryllium-contaminated area.

45. In order to prevent beryllium contamination from being transported to the homes of workers, most beryllium facilities, including Brush Wellman, require that workers remove their clothing and shower prior to leaving work. This prevents workers from carrying contamination home in their hair and on their hands.

Beryllium Processes Associated with the Backward Wave Oscillator (BWO) Lab and Elsewhere at the Raytheon Facility located in Waltham, Mass.

- 46. The areas in which Ms. Suzanne Genereux was employed included the Backward Wave Oscillator Laboratory. During the time that she was employed by Raytheon in the BWO Laboratory (5/82 1989), she reportedly worked on two beryllium pieces associated with the ARCO Windows, which were made of beryllium ceramic. One piece was the window itself and the other was a beryllium copper sleeve associated with the window. The window was a beryllium ceramic piece that was reportedly sandblasted using a small pencil grit blaster. The copper sleeve was honed to fit using a small file if necessary. There may have also been at least one other beryllium part associated with the Tall Man project but the primary beryllium items that she reported were associated with the ARCO Window.
- 47. The beryllium ceramic components that Suzanne Genereux worked with were supplied to the Waltham plant by both Brush Wellman and ABC. The beryllium copper was supplied to Waltham by Hardric Labs (Hardric).

- 48. The operation involving the copper beryllium sleeve was simply a filing operation using a fine bastard file to make the sleeve fit into some stainless steel pieces. Ms, Genereux also indicated that she would sometimes use a Dremel tool and sandpaper to polish the parts. She reported no visible dust associated with the filing of the beryllium copper piece, but Ms Genereux also did not report the use of any control device that was used during this operation. In addition, except for instructions on how to use the file in order to complete the operation, she reported receiving no other training regarding the need for protective equipment. She reported that she was not informed as to the hazards of working with copperberyllium alloy. Ms. Genereux was also not informed regarding the danger of fine filing operations and the respirable dust that would be formed during these filing operations. She was also not informed about the extremely fine particulate that would be generated should a Dremel tool or sandpaper be used with beryllium copper tubing. She was not issued personal protective equipment and only wore work clothes while conducting this operation. She reports that the work required her to file the part close to her breathing zone.
- 49. The second operation conducted by Ms. Genereux was the sandblasting of the ARCO window itself. This operation could be conducted on the window itself or after it had been brazed in order to remove metal from the window. Ms. Genereux indicated that this operation occupied a great deal of her time while she was working in the BWO Laboratory. She indicated that she conducted this operation for periods of time ranging from a few hours per day to

as much as 7 – 8 hours per day. She also reported that each part took approximately 15 – 20 minutes to process.

- 50. Ms. Genereux indicated that she would take the part to a small grit blasting hood and use a pencil grit blaster to remove metal from the part. The grit-blasting hood was reported to have a Plexiglas sash that extended down in the front. The operator would put on protective gloves (reported as Playtex Gloves) and slide their hands under the sash. The operator would then pick up the pencil grit blaster and remove any unnecessary metal, etc from the part. Initially the sash just rested on the wrists of the operator. After a year or so, heavier rubber gloves were attached to the box and some ventilation established. Especially during the first year or so, the box was reportedly not air-tight and a significant amount of dust was observed to come out of the box by several of the employees. The dust was reportedly white in color with a fine consistence. The workers used a compressed air gun to blow the dust off of their clothes.
- 51. Employees working in the area, including Ms Genereux, reported that they did not receive training regarding the hazards of working with beryllium, regarding the prohibition against generating any aerosol (visible or invisible) while working with beryllium, regarding the use of local exhaust control while working with beryllium, regarding the use of work clothes that were changed after working with beryllium, or any other training designed to control their exposures while conducting these operations. Workers were told about keeping the area clean but were not told to wear respiratory protection during dusting operations in the area.

Workers also wore street clothes into these areas and then wore them throughout the rest of the facility, and then home. Ms. Genereux wore her clothes home and commented on the "white dust" present on her clothing when arriving home.

- 52. Beryllium exposures caused by these practices would have been very high at this facility due to these practices. A number of years after the operation had been significantly improved through the use of a contained glove-box, beryllium dust levels in the room were still very high. Samples later taken by Raytheon contractors found levels of beryllium ranging from 0.32 ug/100 cm² to 2.6 ug/100 cm² in the area. The floor and the wall of the room had levels of beryllium that were 0.65 ug/100 cm² and 0.55 ug/100 cm² respectively indicating significant contamination in the room due to the escape of beryllium dust from the grit-blasting containment.
- 53. There are several major rules regarding beryllium operations that were not adhered to during these operations that resulted in high beryllium exposure to Ms Genereux. These practices are:
 - a. Failure to capture the effluent from the processing of either the beryllium ceramic or the beryllium copper alloy at the source of aerosol generation.
 - Failure to provide control methodologies for any processes where beryllium is machined or abraded, whether or not a visible aerosol is generated.

- c. Failure to insist that workers use only approved facilities while working with beryllium components.
- d. Failure to visibly label all beryllium parts with adequate warnings so that these parts will not be used without the proper protection.
- e. Failure to monitor beryllium exposures to beryllium workers to assure that the workers are not being over-exposed to beryllium dust.
- f. Failure to train employees in the use, control, and hazards associated with the handling of beryllium products.
- g. Failure to train and provide protective clothing and respirators for employees working with beryllium materials.
- h. Failure to instruct workers on the potential for carrying beryllium out of the facility to home and the hazards associated with inadvertently taking beryllium dust home on their clothing.
- Failure to provide a room for changing clothes and showering for workers working on beryllium materials.
- j. Failure to label the room as a beryllium area so that other employees know not to enter the room without protective clothing.
- k. Failure to remove compressed air hoses from the room and allowing workers to blow dust off of their clothing resulting in a high exposure to the employee and the re-aerosolization of beryllium dust off of the clothing of the individuals and into the building air.

- I. Failure to assure, by testing and observation, that beryllium dust was being confined to the beryllium area in which it was being used.
- m. Failure to provide for medical testing, on an annual basis, for employees involved in the production of beryllium components.
- 54. It should be noted that all of the above controls were or should have been well-known to the manufacturers of Beryllium products and the beryllium industry in general. In addition, all of these factors were common practice by Brush Wellman, Inc., and ABC, the companies providing beryllium ceramic to Raytheon, as well as by Hardric Labs, supplier of beryllium metal, whose owner was aware of and testified about the associated risks of working with beryllium.

Opinions:

- 55. Beryllium and beryllium compounds have been known to cause disease in humans since the 1930's and chronic beryllium disease has been known to exist since the 1940's. I base this statement on the following information:
 - a. Pulmonary illness associated with beryllium was initially identified in the 1930's by German, Italian, and Russian scientists and in the early 1940's by U.S. scientists. (9) These initial reports were primarily concerned with the acute phase of the disease.

- b. The initial instances of chronic beryllium disease (CBD) were recognized in the fluorescent lamp industry in 1946, where beryllium was utilized in the phosphors of the lamps. (10)
- c. In 1947, a symposium was held in Saranac Lake, New York to discuss the emerging concern regarding pulmonary disease and beryllium. The scientific information presented at this meeting initiated a number of investigations into the health effects of beryllium and, in fact, signaled the beryllium community that pulmonary disease was associated with beryllium exposure. (11)
- d. A study conducted in the 1940's at the Brush Wellman, Inc. facility located in Lorain, Ohio found that individuals living within the community surrounding the plant had developed CBD at distances approaching ¾ of a mile from the plant. Predicted levels of beryllium in the air at the time of the study were approximately 0.01 ug/m³ at the ¾ mile mark. (12)
- 56. Based on the information available at the time, a standard for occupational beryllium exposures was set by the Atomic Energy Commission. The standard was not based on the toxicological properties of beryllium but rather the toxicological properties of lead. This standard is not considered to be protective at this time and has been in question since the mid 1980's. I base this statement on the following information:

- a. In late 1948, Dr. Eisenbud, in conjunction with Willard Machle, (12) developed an exposure standard for beryllium based upon the exposure values for heavy metals and adjusted for the low atomic weight of beryllium (molecular weight of 9). The recommended exposure value was determined by taking the average heavy metal exposure limit (100 ug/m³) and dividing it by 20 (Be has an atomic weight approximately 1/20th of heavy metals). The resulting 5 ug/m³ was reduced to 2 ug/m³ for a safety factor.
- b. Immediately after the setting of the AEC beryllium exposure standard, it seemed that the lowered exposure levels were controlling CBD. In the early 1980's however, CBD returned to the scene. In 1983 three cases of CBD were reported in a spacecraft manufacturing plant. In 1979, Rom et al. found a 15.9% rate of beryllium sensitization among 82 employees at a surface mine and process mill near Delta, UT. A follow-up study in 1982 identified only a sensitization rate of 8.9% in a group of 61 workers, some of whom had been reported as sensitized during the initial study. In 1987, Cullen et al (17) discovered CBD in a precious metal refinery where air concentrations of beryllium were felt to be below the current 2 ug/m³ standard. In 1989 a study by Kreiss et al at a nuclear

weapons plant identified a 11.8% beryllium sensitization rate in 51 machinists with five of the six sensitized individuals having CBD. (18) A second study conducted by Kreiss et al at the same facility, identified a 2% rate of sensitization in nuclear weapons workers with most having actual CBD. (1) In 1993, a third study by Kreiss et al conducted in a ceramics plant identified sensitization rates ranging from 3.5% to 15.8% among tested workers. (16) In a 1996 publication, Kreiss et al found a minimum sensitization rate of 2.7% (19/709) in a plant that reported average exposures to be below the current standard using the DWA method of sampling. (2) A study by Yoshida and Shima, et al (the latter producing similar work implicating health risks below 2 ug/m³ dating back to the 1970's), indicated beryllium sensitized workers in a beryllium copper plant even though exposures were measured to be below the current standard. (20)

- c. Companies working with beryllium have reported cases of CBD in persons who have had no documented or low exposures to beryllium. Cases have been reported in security guards, secretaries, spouses, and other individuals with no documented working exposure to beryllium.
- d. A CBD Case Report prepared by Brush Wellman lists a number of CBD cases and suggests an exposure history for each of these

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individuals. Described in this report are a secretary that primarily walked through plant areas, a clerk typist/secretary that may have spent some bystander time in the production areas, a buyer that was based in the main office building at most times, and a chemist. Exposures for all of these individuals should have been relatively low compared to most production personnel.

- e. The U.S. Department of Energy (DOE) established a Chronic Beryllium Disease Prevention Program in 1999. Among a number of changes, this program set a level of 0.2 ug/m as the action level for DOE facilities. Although this change did not officially change the standard, it signaled that the levels of concern for beryllium are well below the current PEL.
- f. Currently all DOE contractors are requiring respiratory protection for any individual who is or who may be exposed to beryllium above the 0.2 ug/m³ level. At the time this DOE proposal was being considered, Marc Kolanz from Brush Wellman indicated in a presentation that Brush was lowering exposures to ALARA and not just to the 2 ug/m³ OSHA standard.
- g. A paper written by NIOSH has indicated that cases continue to be found in companies where exposures to beryllium are below

- the 2 ug/m³ level. One of the authors on this publication is from Brush Wellman. (24)
- h. Brush Wellman reports in a Health and Safety Update (March, 2002) that five individuals working with beryllium copper in their Reading, PA plant were diagnosed with CBD even though only 3% of all air sample results were above the 2 ug/m³ level.

 Brush is currently suggesting that individuals handling beryllium and beryllium-containing materials in ways which generate particulate utilize engineering and work practice control to keep particulate containing beryllium out of the lungs, off the skin, and off of clothing. In the Tucson plant they are requiring mandatory respiratory protection in processing areas, overgarment protection, skin protection, migration control, process isolation, training and education.
- i. In a 1999 Safety Facts Publication, Brush Wellman indicated that they have adopted the practice of working towards creating a work environment which lowers airborne beryllium exposures and surface/personal contamination to as low as reasonably achievable (ALARA).
- j. In 1998, Dr. Merril Eisenbud, the individual who developed the initial AEC Standard, expressed concern over the observation that with all of the industrial hygiene improvements in beryllium

- manufacturing plants, CBD rates still continued to climb. He states that the data available suggests that "the standard of 2 ug/m³ does not provide the level of protection that was assumed to be the case for many years". (11)
- k. The ACGIH is proposing a lower standard for beryllium⁽²¹⁾ and an authoritative article written by an industrial hygienist for DOE has suggested that the actual exposure limit for beryllium should be 0.1 ug/m³.⁽²²⁾
- I. Brush Wellman and others in the beryllium industry have steadfastly maintained that since OSHA has not changed the standard, it must be protective. As a major federal agency OSHA is very slow to move, yet even OSHA has just released a Request For Information relating to Beryllium published in the Federal Register or 11/26/02. This information has been requested to: "assist the Agency in determining an appropriate course of action regarding occupational beryllium exposure."

 This step is likely an initial step towards lowering the current OSHA PEL.
- m. Even a consultant hired by Brush Wellman, Inc. to comment on another case, has indicated that by the early 1990's, there was a genuine concern among beryllium professionals regarding the safety of the current OSHA standard. In my opinion, Brush

- Wellman, Inc. should have been in the forefront of that movement not at the end of the movement. (Expert Report of Dennis J. Paustenbach, 2/6/2001)
- 57. Current information regarding the relative risk of beryllium particulate exposure to cause CBD may depend more upon particle size or chemical composition than the total mass of the beryllium exposure. I base this statement upon the following information:
 - a. A study that I authored found that over 50% of the beryllium particulate generated in beryllium machining operations were less than 10 um in aerodynamic diameter and that in some operations over 30% of the particles were less than 1 um in aerodynamic diameter. (4)
 - b. We believe that a possible reason for the higher incidence of CBD in beryllium machining operations is due to the smaller particle size of the generated beryllium aerosol. The smaller aerosol size allows deeper penetration into the pulmonary system and the increased surface area may allow better contact with immune system cells.
 - c. A study conducted at the Brush Wellman Inc. Elmore, Ohio

 Facility by Mike Kent et al., a Brush Wellman industrial hygienist
 at the time, compared the incidence of CBD with particle size
 parameters. (25) He concluded that the concentration of particles

- with an aerodynamic diameter of less than 3.5 um may be a more relevant exposure consideration than total mass of beryllium in the air.
- d. A study conducted by Michael McCawley of NIOSH at both the Brush Wellman Elmore Facility and the Reading, PA Facility determined that the particle number concentrations were higher in areas where there was an elevated risk of CBD. (26) Larger particle numbers per mass suggest smaller particle size.
- 58. Although the initial beryllium sampling methodology developed by the Atomic Energy Commission in the 1940's used area samples to predict employee exposures, this method has been shown to consistently underestimate actual exposures. In fact, the beryllium industry, including Brush Wellman and ABC, knew of this limitation and chose to continue to use area sampling knowing that it underestimated worker exposures. The accepted methodology for determining beryllium exposures to individuals is through the use of personal (lapel) monitors. I base this statement on the following information:
 - a. Initial beryllium sampling was conducted using the AEC methodology detailed at the time of the development of the standard in 1949. (23) This methodology utilized high volume samplers to pull air through a 4 inch Whatman #41 filter for analysis. Samples were taken in the breathing zone of the

worker or from general areas around the facility. The samples were normally taken for periods of 15 minutes or so and then sent to the laboratory for analysis. The results of the sampling were then applied to the individuals working at that job task.

Appendix D. of the Brush Wellman, Inc. contract (Plaintiff's Exhibit 32) required that a minimum of 3 breathing zone samples be taken from each job component for each plant operator. Based on the results, a daily-weighted average was calculated by multiplying the average exposure for each job component by the amount of time spent by the operator for each component.

- b. The sum of the products for all of the components for each employee was then divided by the average work time for that employee per day to yield the daily-weighted average for the job. These daily weighted averages were calculated for positions on a quarterly basis.
- c. Although early analytic techniques may have required larger amounts of beryllium on a filter to accurately determine exposures, the AEC DWA method of sampling has several flaws that limit its usefulness in predicting actual exposures. Some of these limitations are as follows:

- i. The AEC method does not measure the exposures of the individual workers but rather measures exposures in areas that the worker frequents. A time and motion study is then done for each group of employees in order to determine the exposure for each individual. Since most employees have different ways to get the same job done, there are usually wide variations in exposure between employees.
- ii. The time in which the area is monitored may not be representative of the actual exposures for that specific task. In some cases, even the best-trained industrial hygienist can miss the worst-case exposure.
- iii. Employees may have significant exposures that are not observed by the industrial hygienist and therefore not sampled. This problem is accentuated by the fact that the AEC sampling methodology requires that the sampling be monitored and employees tend to conduct jobs differently when a representative of management is watching them.
- iv. The AEC method relies upon workers conducting routine and predictable tasks. This methodology is totally inadequate at predicting exposures during non-routine tasks such as maintenance, construction, etc.

- d. In 1978 and 1979 employees at Brush Wellman compared personal monitoring samples (lapel sampling) with the DWA sampling that they had been conducting at Brush facilities. In a memo dated 10/2/78, Mr. P.R. Wilson reported the results of two studies to Mr. Powers. The results of study #1 and study #2 were as follows:
 - i. Study #1 compared the difference between the AEC DWA sampling and a personal sampler. The study concluded that "the AEC DWA method has been underestimating the exposure on most operations. This probably occurs because too few samples are taken of the various components of an operation...."
 - ii. Study #2 compared the difference between two types of OSHA samplers, one with an anti-static cassette. No difference was found between the different samplers.
- e. In March, 1979, Mr. Wilson apparently conducted another test of the difference between the two methodologies and again reported that the lapel sampler gives significantly higher results than did the high volume sampler. (Memo from P.R. Wilson to J.C. Valiquette dated 3/1/79).
- f. Harry M. Donaldson (previously a Brush Wellman employee) and William Stringer compared three methodologies for beryllium

sampling: personal sampling using lapel samplers, the AEC methodology, and personal respirable sampling. The researchers found that none of the three methods were comparable and that the conversion of results from one type of sampling method to another was not possible. They also found that personal samples worn by the workers gave results that were generally higher than were the results obtained using the AEC methodology. In several areas, the geometric means for the personal samples were over 1.5 times higher than the results obtained using the AEC methodology.

- g. The researchers attributed this difference to the difficulty in obtaining good time and motion information for employees, non-typical work tasks, and individual differences. The authors state that based on their research, accurate determination of the exposures of maintenance crews, decontamination workers, and others conducting non-routine jobs cannot be determined using the AEC methodology.
- h. The new DOE Chronic Beryllium Disease Prevention Program

 (CBDPP)⁽¹⁴⁾ requires personal breathing zone samples of all
 persons who work in areas where there may be airborne
 concentrations of beryllium. It requires the employer to employ

- a statistically based program to make the determination of the sample numbers necessary to accurately predict exposures.
- i. Although the CBDPP program is relatively new, the use of personal monitoring and the principals of exposure determination have been known to the profession since the 1970's. The publication "Chemical Hazards in the Workplace" by Proctor and Hughes, published in 1978, states that "In recent years, air sampling has evolved from high-volume sampling, with filter media and absorption in liquid media, to low-volume and low-flow personnel monitoring equipment which workers wear while performing their duties." (25)
- j. The American Industrial Hygiene Association published "A Strategy for Occupational Exposure Assessment" in 1991 that provides several methodologies to design a sampling plan capable of determining employee exposures. (28) This publication also reiterates the belief that area sampling is not a substitute for personal monitoring and that personal monitoring must be done to accurately determine exposures. The book indicates that a mix of full shift sampling and process sampling must be employed to accurately determine processes exposures.
- k. Huey and Materna in their chapter regarding air sampling

 (Fundamentals of Industrial Hygiene) indicate that personal air

- sampling is the preferred method of evaluating worker exposure to airborne chemicals and that area samples are best used to evaluate background concentrations, locate sources of exposure or evaluate the effectiveness of control measures. (29)
- I. Conrad and Soule in their chapter entitled "Principals of Evaluating Worker Exposure" (The Occupational Environment-Its Evaluation and Control) indicate that in order to determine the level of exposure of workers to a given contaminant it is necessary to collect both breathing zone samples and area samples. (30)
- m. The OSHA Technical Manual as well as many of the OSHA

 Standards require that exposure monitoring be conducted using personal monitors in the breathing zone of the worker. This is the only acceptable method in which to determine the actual exposures of individuals since individuals may conduct an operation in many different ways that may influence the exposure to that individual.
- n. The National Materials Board Report in a review of the beryllium industry noted that the Be concentration levels provided by the beryllium manufacturers represent only indications of the workplace concentrations and the trends with time. The report points out that these levels do not represent time-weighted

- averages for the plant work force and are not individual measurements of exposure. The report indicates that the Donaldson paper shows that actual personal exposures may be significantly higher than the DWA exposures taken at the Elmore Plant.
- o. In 1996, Barnard et al ⁽³¹⁾ investigated exposures at the Rocky Flats Nuclear Weapons Plant and found that personal samples were six to seven times higher then were the fixed airhead samples. He also states that the preferred method of exposure assessment is through the use of personal breathing zone samples.
- p. In 1997, Kreiss et al ⁽³²⁾ reported on a study conducted at the Elmore Plant indicating that high levels of exposure were still occurring at the Elmore Plant, the study again looked at the difference between the lapel samples and the DWA samples and again found lapel sample results to be significantly higher than the DWA samples. This paper again emphasized that DWA measurements appear to be a poor estimate of personal exposure. The authors did suggest that factors other than exposure may also play an important role in the risk of beryllium disease.

- q. Based on the results of the NIOSH study, Mr. Gordon Harnett the CEO of Brush Wellman charged a team to address the industrial hygiene practices at Brush Wellman in 1994. This team has suggested sweeping changes in industrial hygiene at Brush Wellman that include modern sampling techniques, additional engineering controls, increased hygiene, and personal protective equipment use that should finally lower exposures at the facility. (Marc Kolanz Affidavit in Ziegler vs. Wellman)
- 59. In my opinion, it was widely known in the beryllium industry that the AEC method of determining worker exposures was likely to minimize exposures at the facility. Management also knew or should have known that better and more accurate methods were available. I base this statement on the following information:
 - a. Management and industrial hygienists at Brush Wellman and ABC had access to and, in fact, had copies of the Donaldson Paper (23) and the National Materials Board Report, both of which indicated that DWI samples resulted in exposures that were lower than those observed when workers wore lapel samplers.
 - b. Philip Wilson, who was the Manager of Safety and Health at Elmore from 1965 to 1989 stated in his deposition of 8/10/00 that when OSHA was instituted in 1970, Brush continued to follow the AEC methodologies. He indicated that they did not try

to determine exposures over any shift for a worker and he indicated that personal sampling did not give good results. He was, however, aware of the NIOSH studies conducted at Brush that suggested that the DWA sampling was not as accurate as the personal samples. Lapel sampling equipment had been available in the plant since 1965 but Mr. Wilson felt that the results were confusing. He did indicate that the lapel sample results were generally 2 – 3 times higher than were the results obtained from the DWA samplers.

- c. In fact, Mr. Wilson actually conducted testing in 1978 and 1979 that indicated that the AEC DWA sampling underestimated the exposures observed when lapel samplers were utilized. He also transmitted this information up to Mr. Powers who was, I believe, a high level manager at the time.
- d. Brush Wellman Management has consistently used the Cardiff experience as the prime example of how well exposure control has resulted in no CBD at the 2.0 ug/m³ exposure level. Mr. Kolanz has indicated that he personally visited the facility to view their program. The Cardiff program, which Brush Management cites as the premier exposure monitoring program, used personal monitoring pumps for each individual entering the beryllium work area since its opening in 1961, almost 40 years

before Brush Wellman finally started using personal monitors to any degree. The Cardiff facility also took some area samples which again were generally lower than the personal sample results. (33)

- e. Although the above information was available to Brush Wellman Management, they did not change to personal monitoring until a final NIOSH study at their Elmore Plant, published in 1997, indicated that "DWA's seem to be a poor estimate of personal exposure, as lapel samples correlated weakly with corresponding quarterly DWA estimates, and lapel samples tended to be higher than the DWA estimates." (32) Only recently has Brush Wellman begun to switch to personal monitoring techniques, almost 30 years after the initial Donaldson study.
- 60. In order to determine the beryllium exposures at a facility, it is necessary to conduct personal sampling of a number of different individuals for each job description at the facility. Failure to conduct proper sampling may result in some individuals receiving very high exposures without their knowledge. I base this statement on the following information:
 - a. Since most employees have different ways to get the same job done, there can be wide variations in exposure between different employees. In addition, the time monitored may not actually be representative of the actual exposures for that task. Employees

- may also have major exposures that are not observed by the industrial hygienist and therefore not sampled.
- b. The American Industrial Hygiene Association published "A Strategy for Occupational Exposure Assessment" in 1991 that provides several methodologies to design a sampling plan capable of determining employee exposures. (28) This publication also reiterates the belief that area sampling is not a substitute for personal monitoring and that personal monitoring must be done to accurately determine exposures. The book indicates that a mix of full shift sampling and process sampling must be employed to accurately determine processes exposures.
- c. The American Industrial Hygiene Association publication entitled "A Strategy for Assessing and Managing Occupational Exposures" indicates that in order to adequately characterize exposures at a facility, similar exposure groups (SEG's) of employees must be determined and then the range of exposures for that group determined through sampling.
- d. The publication indicates that "Area measurements are collected at fixed positions and, therefore, do not accurately reflect the exposure of individuals." The publication also indicates that:

 "The ideal strategy for defining the exposure profile for an environmental agent would be to monitor each worker's

- exposure each day." Although this extensive effort is seldom conducted in workplaces, it is important that enough samples be taken in order to correctly identify the exposure of the individuals working in each SEG. (34)
- e. In the publication entitled "Fundamentals of Industrial Hygiene", the authors indicate; "Differences in work habits of individual workers can significantly affect levels of exposure. Even though several workers are performing essentially the same tasks with the same materials, their individual methods of performing their work could affect the contaminant concentration to which each is exposed." (29)
- f. The DOE Chronic Beryllium Disease Prevention Program requires that employers perform an initial monitoring program that is statistically based to obtain a sufficient number of sample results to adequately characterize exposures. The Program also requires that the exposure levels be determined by conducting personal breathing zone sampling. (14)
- 61. Failure to conduct this type of sampling may result in extremely high exposures to unprotected employees due to the lack of recognition of dangerous tasks. For example, changing HEPA filters in ventilation control systems frequently result in some of the highest exposures that we have found. In the case of the Waltham facility, these jobs were reportedly

conducted with no personal protective equipment and no respiratory protection. It is almost certain that workers at the Waltham Facility would be exposed to beryllium levels in excess of the 2.0 ug/m³ OSHA level accepted by Brush Wellman, Inc. and ABC at this time. I base this statement on the following information:

- a. The sandblasting, filing, and grinding of beryllium materials in an uncontrolled situation almost always results in breathing zone exposures that are well above the current OSHA limit of 2.0 ug/m³.
- b. Later samples taken by Raytheon contractors indicate that the dust from the sandblasting area is contaminated with beryllium and that areas around the sandblasting area were significantly contaminated with beryllium as much as 8 years after more controls were installed in the sandblasting hood.
- c. Visible dust emanating from the sandblasting process was reported by several employees. This as well as assures an exposure well above the current OSHA Limit.
- 62. Brush Wellman, ABC, and Hardric knew or should have known of the high potential for overexposure to beryllium that was occurring at the Raytheon Facility in Waltham, Mass. I base this opinion on the following:
 - a. Brush Wellman, ABC, and Hardric knew of the hazards related to the machining of beryllium in an uncontrolled fashion and

specifically knew about the dangers of sandblasting or gritblasting beryllium parts. This is brought out in the deposition of Mr. Marc Kolanz where he acknowledges that the sandblasting of beryllium parts will result in a high exposure to beryllium. It is also noted in several letters to Raytheon indicating that sandblasting can result in over exposure to beryllium.

- b. Brush Wellman and ABC knew or should have known that
 Raytheon was going to be or was handling beryllium parts since
 they sent a letter to Mr. Bob Demeo, an engineer at Raytheon,
 to inform him of the hazards of beryllium. Although the letter
 invites further inquiry from Raytheon, it does downplay the
 hazards of beryllium handling. The letter cites a "potential
 health risk" if beryllium is abraded to form a finely divided
 airborne particulate. These operations provide a significant
 health risk if conducted in an uncontrolled manner.
- c. Brush Wellman knew or should have known that Raytheon was using a gritblasting technique to clean up beryllia parts. There are several letters from Brush Wellman to Raytheon indicating that sandblasting would be a problem. In October, 1984 Mr. Kolanz warned Mr. John Skowron of Raytheon about sandblasting beryllia and in August 1986 he warns Mr. Peter Salvatore of Raytheon of the same concern. In both letters, he

- downplays the level of concern indicating that this process "can generate airborne beryllium levels above the occupational standard" and says that it "is not recommended". In fact, sandblasting or gritblasting of beryllia in an uncontrolled fashion will result in an over exposure to employees.
- d. Brush Wellman, Inc. sent a form letter to Raytheon and other companies using beryllium ceramic materials that downplayed the danger of the misuse of these materials in 1989 suggesting that there are "few instances" where beryllium particulate is released during the grinding, etc. of beryllia and suggests that it is easily controlled. In fact, it is very difficult to control these exposures and even dust levels in the 2.0 ug/m³ are difficult to see and control.
- e. Brush Wellman also sent a letter to Raytheon in 1989 suggesting that "The only potential safety concern associated with beryllia is the inhalation of significant amounts of respirable beryllium oxide..." In fact, the levels of exposure that cause disease are extremely small and can't even be perceived by the human eye in most cases. These exposures would certainly not be called significant. The same letter indicates that the only risk is to "high concentrations" of particulate. Again, dust exposures of 2

- ug/m³ can't be seen and, in fact, levels as low as 1/10th of that have been linked to chronic beryllium disease.
- f. Both Brush Wellman and ABC provided a significant number of parts to Raytheon and were obviously in the plant on several occasions. It is unlikely that they did not know how these parts were being handled within the facility.
- 63. If Brush Wellman, ABC, and Hardric had assured that Raytheon was utilizing proper beryllium handling techniques, exposures at the Raytheon Waltham Facility would have been mush lower. I base this opinion on the fact that:
 - a. Brush Wellman, ABC, and Hardric had sufficient knowledge on how to control beryllium operations in a gritblasting operation using ventilation controls.
 - b. Brush Wellman and ABC both had employee protection programs that involved the training of employees in the hazards associated with beryllium and included the necessity for employees to change clothes prior to leaving work, use protective ventilation systems, use personal protective equipment, and minimize the exposures to beryllium particulate (even invisible particulate).
- 64. It is my opinion that Brush Wellman, ABC, and Hardric allowed workers at the Raytheon plant at Waltham, Massachusetts facility to be exposed to levels of beryllium that exceeded levels known to cause chronic

beryllium disease. In addition, Brush Wellman, ABC, and Hardric made no attempt to employ available technology at the facility that would have provided more conservative exposure information, or to adequately warn and/or provide information to Raytheon that would have ensured a safe environment for Raytheon employees, including Suzanne Genereux.

- 65. Hardric Labs likewise failed to provide any warnings that abrading the beryllium copper rings it supplied to the Waltham plant would generate particulate sufficient to place Suzanne Genereux and others at risk for exposures that could cause chronic beryllium disease.
- 66. The warnings employed by Brush Wellman and ABC were inadequate in communicating the risks and methods to be employed to reduce the health risks of exposure to beryllium. I base this statement on the following:
 - a. In the deposition testimony of Marc Kolanz (of Brush Wellman) and Dino Nicoletta (of ABC) as representatives of their respective companies describe the warnings that were produced and might have been sent at one time to Raytheon. The warning labels appearing in exhibits did not accompany the subject products in Ms. Genereux's possession.
 - b. The Material Safety Data Sheets supplied by Brush Wellman, Inc. in the early 1980's (Kolanz Exhibit 4) provide extremely poor hazard information regarding exposures to beryllium ceramic. These MSDS

state that "Inhalation of excessive amounts of respirable beryllium may cause serious, chronic pulmonary illness." Two milligrams per cubic meter of dust is invisible and certainly would not be considered to be an "excessive amount" of dust. In addition the MSDS simply says that local exhaust is required for operations generating airborne material. Polishing, for example, would not be an operation that most would consider an dust generating process, yet polishing beryllium can result in extremely high exposures.

- c. A second MSDS dated 4-7-83 again is only concerned with "excessive amounts of respirable beryllium". Very few processes would be considered to produce excessive amounts of dust. The MSDS also indicates that "operations generating airborne material should be air sampled" when, in fact, all operations involving beryllium materials should be sampled. In fact, all operations at the Brush Wellman Facilities were being monitored using air sampling techniques.

 Considering the extremely low allowable exposure levels (even the OSHA level is extremely low) all processes should be monitored.
- d. The MSDS for beryllium ceramic generated by Brush Wellman dated 10-08-85 indicates that no protective equipment is necessary when handling solid forms but that a respirator must be used if air concentrations exceed the OSHA standard. Again, there is no warning that any process that even disturbs the surface of the product may

- result in an over exposure. The wording on the MSDS attempts to list several operations that would be expected to result in high exposures but fails to list many others such as polishing. In general, any process that disturbs the surface can produce levels of exposure that are above the OSHA level and able to cause sensitization and disease.
- e. It is not until the 1990 revision of the MSDS that Brush Wellman finally states that any abrading of the surface will generate a hazardous particulate. Even in that case, however, the first sentence becomes confusing since it states that "In solid form, this product is completely safe under normal conditions of use". This is somewhat misleading since the altering the product may be a normal use for a company. It is not until this revision, however, that much of the information regarding the use of beryllium is presented. This revision would not have been viewed by Ms. Genereux, since she would have been leaving the beryllium area by this time. Virtually everything presented in the 1990 version of the MSDS was known in the early 1980's and could have been put into previous documents.
- f. The earlier MSDS also needed to direct users and management to use protective clothing protocols and procedures of greater specificity so as not to lead to contamination of other areas and other people and reexposing themselves.

- g. A major concern regarding all of Brush Wellman MSDS's and warning letters is that they did not advise employers and employees that the OSHA Permissible Exposure Level is so low that the over exposure level may be invisible to the naked eye. Employees cannot see the dust levels that could cause them beryllium disease or sensitization. The MSDS's needed to inform employers and employees that if the surface is disturbed in any way during a manufacturing process (e.g., as in filing or sandblasting, or other methods like this), it must be closely monitored to assure that employees are not exposed to levels of beryllium that will cause harm.
- h. Another concern is that the MSDS's did not warn employers and employees that any clothing worn in a beryllium manufacturing area needs to be removed and kept out of "clean" areas (and disposed of or laundered in some way) in order to protect other workers and family members at home. The ability for clothing contaminated with beryllium to cause illness in family members had been demonstrated in the late 1940's through the 1960's. This information was not new information, yet it did not become part of the Brush Wellman MSDS's until 1990.
- 67. The ABC MSDS's essentially copy the MSDS's provided by Brush Wellman (see Nicoletta, pp. 109-111). A comparison of the companies' MSDS's

confirms this observation. All of the comments regarding the Brush Wellman MSDS's therefore apply to the ABC MSDS's.

68. <u>Brush Wellman Warning Labels</u>

- a. Two separate labels that accompanied packaging of beryllium pre- and post-1985 time period when shipped from Brush Wellman are shown in Exhibits 3 and 2 in Kolanz's deposition, respectively. These labels state at the top "Metalized Beryllia Ceramic, Danger—Inhalation of Dust or Fumes May Cause Serious Chronic Lung Disease." However, these labels suffer considerably from their apparent failure to reach the end users like Ms. Genereux at the Raytheon Waltham facility. The label was not passed forward through the chain of handlers in Raytheon. It was not delivered and there is nothing on the label that indicates that the labeling must be kept with the product. Representatives of Brush Wellman apparently visited the Waltham plant and saw or were aware of the lack of warnings within the beryllium processing areas.
- b. This information is not provided until the advent of the 1990 MSDS even though this information was known previous to that time.

69. ABC Warning Labels

a. The ABC labels were apparently copied from Brush Wellman's labels or both copied another source. I reiterate my opinion regard these labels as commented on Brush Wellman's labels earlier. There is no date for these labels but the time frame for Brush Wellman's labels was probably post 1985 when OSHA required cancer labels and MSDS's for beryllia (and nickel) containing products.

b. One of the ABC labels states:

"BERYLLIUM PRODUCT

POTENTIALLY HAZARDOUS MATERIAL

Care should be taken inhaling dust or fumes. Secondary operations which can generate dust or fumes (such as abrading, chemical etching, lapping, grinding, scoring, or firing over 10000°C) must be performed in facilities which meet OSHA standards.

i. This label does not adequately communicate the dangers of ABC's products in several respects: (a) it is pure text -- icons, pictorials and graphics could have been used to facilitate noticeability and convey hazardousness; (b) it does not adequately tell the end user that the maximum dangerous airborne level is so small in particulate size and amount, that the level of airborne particles that could cause lung scarring and chronic disease is invisible (as people may think breathing considerable amounts of dust is needed before it is problematic), and (c) it does not tell what can happen if dust and fumes are inhaled (i.e., that they are risking getting lung disease).

Although other labels discussed in this affidavit tell about the

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potential of Chronic Lung Disease, this one does not.

Consequences information helps to motivate compliance to warning directives, to energize people to avoid a severe hazard.

70. The risks from the use of beryllium and beryllium-containing materials was known and knowable by Brush Wellman, ABC, and Hardric. However, the warning materials supplied by Brush Wellman, ABC, and Hardric with their beryllium-containing products did not adequately communicate warnings and instructions. They failed to provide the users of those products, including Suzanne Genereux, with information about the nature and extent of the dangers associated with the use or foreseeable misuse of their beryllium-containing products. The warning labels and other documents such as the MSDS's that the Defendants supposedly placed into the chain of commerce did not provide adequate information so as to avoid foreseeable risks.

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References

- 1. Kreiss, k., Mroz, M.M., Zhen, B., Martyny, J.W., Newman, L.S. 1993. Epidemiology of beryllium sensitization and disease in nuclear workers. Amer. Rev. Respir. Dis. 148:985 991.
- 2. Kreiss, K., Mroz, M.M., Newman, L.S., Martyny, J., Zhen, B. 1996. Machining risk of beryllium disease and sensitization with median exposures below 2 ug/m³. Amer. J. of Ind. Med. 30:16 25.
- 3. Sanderson, W., Henneberger, P., Martyny, J., Ellis, K., Mroz, M., Newman, L. 1999. Beryllium Contamination Inside Vehicles of Machine Shop Workers. Applied Occ. and Environ. Hyg. 14:223 230.
- 4. Martyny, J., Hoover, M., Mroz, M., Ellis, K., Bartleson, B., Maier, L., Newman, I. 1999. Aerosols Generated During Beryllium machining. J. Occ. Env. Med. 42(1): 8 18.
- 5. Kelleher, P.C., Martyny, J.W., Mroz, M.M., Maier, L.A., Ruttenber, A.J., Young, D.A., Newman, L.S. 2001. Beryllium Particulate Exposure and Disease Relations in a Beryllium Machining Plant. Journal of Occ. And Environ. Med. 43(3) 238 249.
- 6. LaMontagne, A.D., Van Dyke, M.V., Martyny, J.W., Ruttenber, A.J. 2001. Cleanup Worker Exposures to Hazardous Chemicals at a Former Nuclear Weapons Plant: Piloting of an Exposure Surveillance System. Applied Occup. Environ. Hygiene 16(2): 284 290.
- 7. LaMontagne, A.D., Van Dyke, M.V., Martyny, J.W., Simpson, M.W., Holwager, L.A., Clausen, B.M., Ruttenber, A.J. 2002. Development and Piloting of an Exposure Database and Surveillance System for DOE Cleanup Operations. AIHAJ 63(2) 213 224.
- 8. Rossman, M.D., Preuss, O.P., Powers, M.B. 1991. *Beryllium: Biomedical and Environmental Aspects*. Williams and Wilkins, Baltimore, MD. 301 pp.
- 9. Eisenbud, M. 1998. Vignettes in the History of Beryllium Disease Part I: Reports of Beryllium Toxicity prior to the Second World War. Appl. Occup. Environ. Hyg. 13(1) 18 20.

- 10. Eisenbud, M. 1998. Vignettes in the History of Beryllium Disease Part II. The Early 1940's: The Search for a Common Denominator. Appl. Occup. Environ. Hyg. 13(4) 221 226.
- 11. Eisenbud, M. 1998. The Standard for Control of Chronic Beryllium Disease. Appl. Occup. Environ. Hyg. 13(1) 25 31.
- 12. Eisenbud, M. 1982. Origins of the Standards for Control of Beryllium Disease (1947 1949). Environ. Res. 27: 79 88.
- 13. National Institute for Occupational Safety and Health. 1972. Occupational Exposure to Beryllium. U.S. Dept. of Health, Education, and Welfare. NIOSH. Washington, D.C.
- 14. U.S. Department of Energy. 1999. Chronic Disease Prevention Program; Final Rule. 10 CFR Part 850. Federal Register, December 8, 1999.
- 15. Johnson, N.R. 1983. Beryllium Disease among Workers in a Spacecraft Manufacturing Plant California. Morbidity and Mortality Weekly Report 32(32) 419.
- 16. Rom, W.N., Lockey, J.E., Bang, K.M. 1983. Reversible beryllium sensitization in a prospective study of beryllium workers. Arch. Environ. Health 38: 302-307.
- 17. Cullen, M., Kominsky, J., Rossman, M. et. al. 1987. Chronic beryllium disease in a precious metal refinery. Am. Rev. Respir. Dis. 135: 201 208.
- 18. Kreiss, K., Newman, L.S., Mroz, M.M., Campbell, P.A. 1989. Screening blood test identifies subclinical beryllium disease. J. Occup. Med. 31: 603 608.
- 19. Kreiss, K., Wasserman, S., Mroz, M., Newman, L., 1993. Beryllium Disease Screening in the Ceramics Industry: Blood Lymphocyte Test Performance and Exposure-Disease Relations. J. Occup. Med. 35: 267 274.
- 20. Yoshida, T., Shima, S., Nagaoka, K. et.al. 1997. A study on the beryllium lymphocyte transformation test and the beryllium levels in the working environment. Ind. Health 35: 374 379.

- 21. American Conference of Governmental Industrial Hygienists. 2006. 2006 TLV's and BEI's: Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices. ACGIH. Cincinnati, OH 222pp.
- 22. Wambach, P.F. and Tuggle, R.M. 2000. Development of an Eight-Hour Occupational Exposure Limit for Beryllium. Appl. Occup. Environ. Hygiene 15(7): 581 587.
- 23. Donaldson, H.M. and Stringer, W.T. 1980. Beryllium Sampling Methods. Amer. Ind. Hyg. Assn. J. 41: 85 90.
- 24. Stefaniak, A.B., Hoover, M.D., Dickerson, R.M., Peterson, E.J., Day, G.A., Breysse, P.N., Kent, M.S., Scripsick, R.C. 2003. Surface Area of Respirable Beryllium Metal, Oxide, and Copper Alloy Aerosols and Implications for Assessment of Exposure Risk of Chronic Beryllium Disease. AIHA Journal 64:297 305.
- 25. Kent, M.S., Robins, T.G., Madl, A.K. 2001. Is Total Mass or Mass of Alveolar-Deposited Airborne Particles of Beryllium a Better Predictor of the Prevalence of Disease? A Preliminary Study of a Beryllium Processing Facility. Applied Occ. And Environ. Hygiene 16(5) 539 – 558.
- 26. McCawley, M.A., Kent, M.S., Berakis, M.T. 2001. Ultrafine Beryllium Number Concentration as a Possible Metric for Chronic Beryllium Disease Risk. Applied Occ. And Environ. Hygiene 16(5) 631 638.
- 27. Proctor, N.H., Hughes, J.P. 1978. *Chemical Hazards of the Workplace*. J.B. Lippincott. Philadelphia, PA. 533 pp
- 28. Hawkins, N.C. Norwood, S.K., Rock, J.C. 1991. *A Strategy for Occupational Exposure Assessment*. American Industrial Hygiene Assoc. Fairfax, VA 179pp.
- 29. Plog, B.A. and Quinlan, P.J. ed. 2002. *Fundamentals of Industrial Hygiene*. National Safety Council. 1080 pp.
- 30. DiNardi, S.R. ed. 1997. The Occupational Environment Its Evaluation and Control. American Industrial Hygiene Association. Fairfax, VA. 1365pp.

- 31. Barnard, A.E., Torma-Krajewski, J., Viet, S.M. 1966. Retrospective Beryllium Exposure Assessment at the Rocky Flats Environmental Technology Site. Amer. Indust. Hygiene J. 57: 804 – 808.
- 32. Kreiss, K., Mroz, M., Zhen, B., Wiedemann, H. et. al. 1997. Risks of beryllium disease related to work processes at a metal, alloy, and oxide production plant. Occup. Environ. Med. 54: 605 612.
- 33. Johnson, J.J., Foote, K., McClean, M., Cogbill, G. 2001. Beryllium Exposure Control Program at the Cardiff Atomic Weapons Establishment in the United Kingdom. Applied Occ. Env. Hygiene. 16(5) 619 630.
- 34. Mulhausen, J.R. and Damiano, J, Ed. 1998. A Strategy for Assessing and Managing Occupational Exposures. American Industrial Hygiene Assoc. Fairfax, VA. 349pp.